IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	**US 6,143,771**
Issued:	**November 7, 2000**
To:	**Per Lennart Lindberg; Sverker von Unge**
For:	**COMPOUNDS**

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this paper is being transmitted via the Electronic Filing System to the U.S. Patent and Trademark Office on the date indicated below.

/John M. Genova/	32,224
Signature	Reg. No.
John M. Genova	24 June 2011
Attorney's Name	Date

Commissioner for Patents
Alexandria, VA 22313-1450

PETITION UNDER 37 §1.183
TO RECONSIDER FINAL DETERMINATION ON
APPLICATION FOR PATENT TERM EXTENSION

PETITION UNDER 37 §1.183
TO RECONSIDER FINAL DETERMINATION ON
APPLICATION FOR PATENT TERM EXTENSION

Sir:

Applicant's application for patent term extension ("PTE Application") was denied by the USPTO in separate Decisions dated July 28, 2005, and September 12, 2007, on grounds that subsequently were determined by the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") to be incorrect. In view of the Federal Circuit's decision in PhotoCure v. Kappos, 603 F.3d 1372 (Fed. Cir. 2010), the PTE Application is eligible for patent term extension. In this extraordinary situation, the Director is requested under 37 C.F.R. §1.183 to suspend or waive the rules and enter this request for reconsideration of the USPTO's negative decision in view of PhotoCure.

A. Background

On May 25, 2005, AstraZeneca AB ("Applicant") filed a PTE Application under 35 U.S.C. §156(d)(1) and 37 C.F.R. §1.720(f) with the USPTO in compliance with 37 C.F.R. §1.740 to extend the term of U.S. Patent No. 6,143,771 (the "'771 patent"). The '771 patent claims the approved product NEXIUM® I.V. (esomeprazole sodium) and methods of using and manufacturing NEXIUM I.V. The '771 patent is still in force and has an expiration date of May 27, 2014.

In both Decisions, the USPTO alleged that the '771 patent is not eligible under 37 C.F.R. §156a)(5)(A) on the grounds that the same active moiety of NEXIUM I.V. was also present in a previously approved product, NEXIUM® (esomeprazole magnesium). Therefore, according to the USPTO, NEXIUM I.V. was not the first permitted commercial marketing or use of the product as required by 37 C.F.R. §156(a)(5)(A). Applicant requested reconsideration of the first Decision mailed July 28, 2005, but did not request reconsideration of the second Decision mailed September 12, 2007.

In PhotoCure, the USPTO had denied PhotoCure's application to extend the patent term of U.S. Patent No. 6,034,267 (the "'267 patent"), which was filed under 35 U.S.C. §156 on September 20, 2004. The position of the USPTO was that METVIXIA® (methyl

aminolevulinate hydrochloride) was not the first permitted commercial marketing or use of the product as required by 37 C.F.R. §156(a)(5)(A) because the same active moiety of METVIXIA was also present in a previously approved product LEVULAN (aminolevulinic acid HCl).

The Federal Circuit in PhotoCure rejected the USPTO's denial of patent term extension for the '267 patent and held that the USPTO's interpretation of "product" in 35 U.S.C. §156 to mean "active moiety" was incorrect in view the court's previous decision in Glaxo v. Quigg, 894 F.2d 392 (Fed. Cir. 1990). Specifically, the Federal Circuit in PhotoCure stated that "[i]n Glaxo this court held that 'product' in §156(a) means the product that is present in the drug for which federal approval was obtained," Id. at 1376 (citing to Glaxo at 894 F.2d at 393-95). Additionally, the PhotoCure court pointed out that it had held, in Hoechst-Rousses Harms., Ink's. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997), that "[f]or purposes of patent term extension, this active ingredient must be present in the drug product when administered." PhotoCure at 1376.

Applying the Glaxo and Hoechst analyses, the Federal Circuit determined that the '267 patent is eligible for PTE. The active ingredient of METVIXIA is methyl aminolevulinate hydrochloride, i.e., the substance for which federal approval was obtained and which is physically present in the final dosage form. Neither it, nor any salt or ester of methyl aminolevulinate hydrochloride had been approved prior to the approval of METVIXIA. The grant of permission to commercially market or use METVIXIA is, therefore, the first permitted commercial marketing or use of the product/active ingredient as required by section 156(a)(5)(A).

Attached is a copy of each of the USPTO's letters dated October 27, 2010 and November 2, 2010, respectively, to FDA acknowledging the eligibility of the '267 patent for patent term extension and requesting FDA's assistance in confirming that other requirements of section 156 under the purview of the FDA have been satisfied.

B. Regulatory Basis for Relief

The '771 patent is still in force and has an expiration date of May 27, 2014. In the PTE Application, it is stated that the length of extension of patent term claimed by Applicant is 793 days, which would extend the original expiration date of the '771 patent to July 28, 2016.

Section 156 is fundamentally remedial in nature and is to be construed liberally. It serves the function of restoring a period of exclusivity that is rightfully due to the patentee of a

pharmaceutical invention that the patentee was precluded from enjoying in the marketplace during the regulatory review. 37 C.F.R. §1.183 which provides in relevant part that "[i]n an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director..." It is an extraordinary situation when the Federal Circuit issues a decision that directly affects a decision made the USPTO.

The time period available under 37 C.F.R. §1.750 for requesting reconsideration of the USPTO's second Decision, mailed September 12, 2007, has expired. However, in view of the a) fact that there is no provision prohibiting the USPTO from accepting a request for reconsideration, even if untimely, and b) this extraordinary situation where the Federal Circuit has decided a key issue that should undo a USPTO denial, the USPTO should waive its usual deadline for requests for reconsideration.

C. The '771 Patent Is Eligible for Patent Term Extension.

In addition to the PTE Application itself and the Applicant's request for reconsideration of the USPTO's first Decision dismissing the PTE Application, Applicant relies on the decision in PhotoCure and submits that the '771 patent is eligible for patent term extension.

The active ingredient of NEXIUM I.V. is esomeprazole sodium. Neither it, nor any salt or ester of esomeprazole sodium has been approved previously by the FDA. Because no salt or ester of esomeprazole sodium has been approved prior to NEXIUM I.V., the grant of permission to commercially market or use NEXIUM I.V. is the first permitted commercial marketing or use of the product/active ingredient as required by section 156(a)(5)(A). Accordingly, the '771 patent is eligible for extension under the provisions of section 156.

Authorization is given to charge the any required fee in connection with this communication, to Deposit Account No. 23-1703.

Respectfully submitted,

Dated: 24 June 2011

/Leslie Morioka/
Leslie Morioka
Reg. No. 40,304

Attorney for Applicant

WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113
lmorioka@whitecase.com

Attachment: Copy of each of USPTO letters to FDA dated October 27, 2010 and November 2, 2010, respectively, in the matter of PTE application regarding U.S. 6,034,267

ATTACHMENT

UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 27 2010

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

This is in regard to the application for patent term extension for U.S. Patent No. 6,034,267 filed by PhotoCure ASA under 35 U.S.C. § 156 on September 20, 2004.

The Federal Circuit decided that U.S. Patent No. 6,034,267 was eligible for patent term extension under 35 U.S.C. § 156. The dispute involved compliance with section 156(a)(5)(A). The position of the USPTO was that Metvixia was not the first permitted commercial marketing or use of the product as required by section 156(a)(5)(A) based on the theory that the same active moiety of Metvixia as was also present in a previously approved product, Levulan. The position of PhotoCure was that the statute does not refer to "active moiety," rather the statute refers to active ingredient. PhotoCure asserted that the active ingredient of Metvixia is different than the active ingredient of Levulan. In *Photocure v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010), the court relied on its previous decision in *Glaxo v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990) (*Glaxo II*) for its determination of eligibility of Photocure's Metvixia product. Specifically, the Federal Circuit in *Photocure* stated that "[i]n *Glaxo* this court held that 'product' in §156(a) means the product that is present in the drug for which federal approval was obtained," *Id.* at 1376. (citing to *Glaxo II* at 894 F.2d at 393–95). Thus, *Glaxo II* is highly instructive in determining when an active ingredient, which may contain the same active moiety as a previously approved active ingredient, is eligible for extension.

In *Glaxo II*, the Federal Circuit affirmed the district court's determination that a patent which claimed an ester of cefuroxime was eligible for extension regardless of previous approvals of two salts of cefuroxime. *Glaxo II* at 393. Although the *Glaxo II* court did not explicitly set forth its rationale for determining that the patent was eligible for extension under 156, in affirming the district court, the Federal Circuit implicitly adopted the district court's rationale. There, the district court in *Glaxo v. Quigg*, 706 F. Supp 1224 (E.D. Va. 1989) (*Glaxo I*) framed the rationale for eligibility as:

> the question sharply presented is whether the "product" referred to in (a)(5)(A) is cefuroxime axetil, on the one hand, or cefuroxime, the parent acid on the other. The answer to this question turns on the statutory definition of "product." Subsection (f) of Section 156 defines "product" as "a drug product," which, in turn, is defined as follows:
>
> > (2) The term "drug product" means the active ingredient of a new drug, antibiotic drug, or human biological product

> (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.
>
> *35 U.S.C. §156(f)(2).*
>
> The central question then is whether the active ingredient of Ceftin Tablets is the ester cefuroxime axetil or the parent acid cefuroxime. If the former is true, plaintiff is entitled to an extension of its patent term. If the latter is true, then no extension would be warranted because the FDA has previously approved NDA's for Zinacef and Kefurox, two sodium salts of cefuroxime.

Glaxo I at 1227.

Additionally, the *Photocure* court pointed out that they held in *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997) that "[f]or purposes of patent term extension, this active ingredient must be present in the drug product when administered." *Photocure* at 1376. Thus, the active ingredient of Photocure's Metvixia product is methylaminolevulinate hydrochloride, because that is the substance physically present in the final dosage form.

Applying the *Hoeschet* and *Glaxo I* analyses here, the active ingredient of Metvixia is methyl aminolevulinate hydrochloride. Neither it, nor any salt or ester of methyl aminolevulinate hydrochloride has been previously approved by FDA. Because no salt or ester of methyl aminolevulinate hydrochloride had been approved prior to the approval of Metvixia, the grant of permission to commercially market or use Metvixia is the first permitted commercial marketing or use of the product/active ingredient as required by section 156(a)(5)(A). Accordingly, the '267 patent is eligible for extension under the provisions of section 156.

Based on the Federal Circuit's finding that the '267 patent is eligible for extension, the assistance of your Office is requested in confirming that the product identified in the application, METVIXIA® (methylaminolevulinate hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Kenyon & Kenyon
One Broadway
New York, NY 10004

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

NOV - 2 2010

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Further to our letter of October 27, 2010, the USPTO has determined that U.S. Patent No. 6,034,267 claims the new drug product, METVIXIA® (methylaminolevulinate hydrochloride) which, according to FDA's letter of March 7, 2007, was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. As per our letter of October 27, 2010, the subject patent was determined to be eligible for patent term extension in *Photocure v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Kenyon & Kenyon
One Broadway
New York, NY 10004

RE: METVIXIA® (methylaminolevulinate hydrochloride)
Docket No. FDA-2007-E-0104